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(54) Title: A DISPOSABLE, WEARABLE INSULIN DISPENSING DEVICE, A COMBINATION OF SUCH A DEVICE AND A PROGRAMMING CONTROLLER AND A METHOD OF CONTROLLING THE OPERATION OF SUCH A DEVICE

(57) Abstract: A disposable, wearable, self-contained insulin dispensing device comprising a housing 2, an insulin source in said housing and adapted for pumping insulin from said insulin source to a catheter 8 for injection of insulin in a user of the device, the catheter being associated with the housing and projecting generally perpendicularly to a generally planar surface of the housing intended for abutting a skin surface of the user, an adhesive layer 11 being provided on the planar surface for adhering the surface to the skin surface, and a removable release sheet 12 covering the adhesive layer for protecting the adhesive layer prior to use of the device, the release sheet being provided with catheter protection means 13 to enclose and protect an end portion of the catheter such that removal of the release sheet for exposing the adhesive layer exposes the end portion, and the pump means comprising an actuator comprising a shape memory alloy wire.

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A DISPOSABLE, WEARABLE INSULIN DISPENSING DEVICE, A COMBINATION OF SUCH A DEVICE AND A PROGRAMMING CONTROLLER AND A METHOD OF CONTROLLING THE OPERATION OF SUCH A DEVICE

5 The present invention relates generally to wearable medicine, particularly insulin dispensing devices.

In connection with injection of insulin for treating Type I and Type II Diabetes extremely important features are simplicity of operation, reliability, cost and
10 flexibility, which all are related to the issue of compliance which particularly in the cases of relatively mild Type II diabetes is a problem with important consequences regarding the success rate in treating the patients.

The main object of the invention is to provide a wearable medicine, particularly
15 insulin dispensing device having features and operation characteristics supporting and easing compliance by the users of the device.

The present invention provides a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising
20 - a housing,
- an insulin source in said housing,
- a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device and, said catheter being associated with said housing and projecting generally
25 perpendicularly to a generally planar surface of said housing intended for abutting a skin surface of a user of the device,
- an adhesive layer provided on said planar surface for adhering said planar surface to said skin surface, and
- a removable release sheet covering said adhesive layer for protecting said
30 adhesive layer prior to use of said dispensing device, said release sheet being provided with catheter protection means to enclose and protect an end portion of said catheter such that removal of said release sheet for exposing said adhesive layer exposes said end portion.

Hereby, in a simple, reliable and cost-effective manner a device is provided which is easy to apply and still in an effective manner protects the catheter against damage and contamination until use of the device is initiated.

- 5 In another aspect, the invention provides a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising
- a housing,
 - an insulin source in said housing,
 - a pump means in said housing and adapted for pumping insulin from said
- 10 insulin source to a catheter for injection of said insulin in a user of the device and, said catheter being associated with said housing and projecting generally perpendicularly to a generally planar surface of said housing intended for abutting a skin surface of a user of the device,
- an adhesive layer provided on said planar surface for adhering said planar
- 15 surface to said skin surface,
- a combined microphone and loudspeaker associated with said housing, preferably arranged inside said housing, and
 - recording and play back means connected to said combined microphone and loudspeaker and associated with said housing, preferably arranged inside said
- 20 housing, such that verbal messages may be recorded and played back by said dispensing device.

Hereby a device promoting simple communication between a health care provider and the user is provided with readily understandable operation and

25 with good effect on the compliance rate.

- In yet another aspect, the invention provides a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising
- a housing,
- 30 - an insulin source in said housing,
- a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device, and

- an actuator for said pump means, said actuator comprising a shape memory alloy wire, said actuator preferably further comprising a ratchet gear or pawl wheel, a pawl adapted for co-operating with said pawl wheel and connected to one end of said shape memory alloy wire and a spring means connected to
- 5 said pawl, the connections between said pawl and said wire and said pawl and said spring means being such that contraction of said wire rotates said pawl wheel against the spring force of said spring means.

Hereby a pump means requiring very low energy and with a high degree of

10 reliability is provided at a relatively low cost.

In a yet further aspect, the invention relates to a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising

- a housing,
- 15 - an insulin source in said housing,
- a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device,
- an actuator for said pump means, preferably an actuator comprising a shape memory alloy wire, and
- 20 - controlling means for controlling the operation of said actuator according to a programme, said programme consisting in a sequence of a certain amount of actuations of said actuator per 24 hours time periods, or, in connection with provision of a timing means connected to said controlling means said programme consisting in a sequence of actuations of said
- 25 actuator that varies according to the time of day or, in connection with provision of a timing means connected to said controlling means and an input device for inputting data to said controlling means, adapting said controlling means so as to be programmable by means of said data, or adapting said programme of said controlling means to comprises algorithms
- 30 for automatically altering the sequence of actuations of said actuator according to input of data relative to actual glucose level in the blood of the use of the device and/or intake of nutrients by said user.

Hereby, compliance is enhanced by providing a device with capabilities of rendering a very specific and well-tuned dosage which may be altered according to the specific development of the individual user.

- 5 So as to achieve a compact dispensing device, the pump means may comprise a piston rod for displacing a piston in a cylindrical container of said medicine to be dispensed and an actuator for displacing said piston rod, wherein said piston rod is configured such that the portion of said piston rod between said actuator and said piston is rectilinear and rest of said piston rod is arcuate, and
10 such piston rod may comprise elements arranged in a row and interconnected by hinge elements, wherein each element is provided with a surface spaced from said hinge element and configured to abut a corresponding surface of an adjacent element when said piston rod is rectilinear, and said elements may be provided with screw threads on the outer surface thereof for co-operating with
15 corresponding screw threads of the actuator.

In an alternative embodiment such piston rod may comprise a strip having an arcuate cross section taken transverse to the longitudinal direction of said strip which is rectilinear between said actuator and said piston while the rest of the
20 strip is wound into a roll. The strip may be provided with apertures, preferably transversely extending slits, evenly spaced along the length thereof for receiving corresponding projections of said actuator.

In a yet further aspect, the invention relates provides a combination of a
25 dispensing device as specified above and a programming controller, said dispensing device and said programming controller comprising co-operating transmission and/or receiving means for mutual communication of data, said programming controller preferably being a cellular telephone or a personal computer or a laptop computer or a hand held computer.

30

Moreover, the invention provides a method of controlling the operation of a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising

- a housing,
 - an insulin source in said housing,
 - a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device,
 - 5 - an actuator for said pump means, preferably an actuator comprising a shape memory alloy wire, and
 - controlling means for controlling the operation of said actuator according to a programme,
- said method comprising the steps of:
- 10 - providing said controlling means with data for generating and/or amending said programme prior to and/or after initiation of use of said dispensing device.

Furthermore, in a yet other aspect, the invention also relates to a method of controlling the operation of a disposable, wearable, self-contained medicine,

15 particularly insulin dispensing device comprising

- a housing,
 - an insulin source in said housing,
 - a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device
 - 20 and, said catheter being associated with said housing and projecting generally perpendicularly to a generally planar surface of said housing intended for abutting a skin surface of a user of the device,
 - an adhesive layer provided on said planar surface for adhering said planar surface to said skin surface,
 - 25 - a combined microphone and loudspeaker associated with said housing, preferably arranged inside said housing,
 - recording and play back means connected to said combined microphone and loudspeaker and associated with said housing, preferably arranged inside said housing, such that verbal messages may be recorded and played back by said
 - 30 dispensing device, an
 - manual operating means for manually controlling the operation of said dispensing device
- said method comprising the steps of:

- recording verbal instructions in said recording means for instructing the user of the device in the operation of said dispensing device, and
 - playing back said verbal instructions.
- 5 Finally, the invention relates to a method of controlling the operation of a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising
- a housing,
 - an insulin source in said housing,
 - 10 - a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device and, said catheter being associated with said housing and projecting generally perpendicularly to a generally planar surface of said housing intended for abutting a skin surface of a user of the device,
 - 15 - an adhesive layer provided on said planar surface for adhering said planar surface to said skin surface,
 - a combined microphone and loudspeaker associated with said housing, preferably arranged inside said housing,
 - a programmable computing means associated with said housing, preferably
 - 20 arranged inside said housing, and
 - signal conversion means connected to said combined microphone and loudspeaker and associated with said housing, preferably arranged inside said housing, and adapted for converting received audio signals into input signals for said computing means and for converting output signals from said
 - 25 computing means to audio signals,
- said method comprising one or more of the steps of:
- transmitting audio signals to said microphone for controlling the operation of said dispensing device,
 - receiving audio signals from said loudspeaker for evaluating the operation of
 - 30 said dispensing device.

In the following, the invention will be described and explained more in detail in connection with various embodiments of an insulin dispensing device according

to the invention shown, solely by way of example, in the accompanying drawings where:

Fig. 1 is a schematic isometric view of a first embodiment of a disposable
5 insulin dispensing device according to the invention before the adhesive pad for
adhering the device to the skin of a user has been mounted on the device,

Fig. 2 is a schematic isometric view of the device of Fig. 1 seen from another
angle and with the adhesive pas mounted thereon,
10

Fig. 3 is a schematic isometric partly exploded view of the device of Fig. 2,

Fig. 4 is a schematic entirely exploded view of the device of Fig. 2,

15 Fig. 5 is a schematic isometric view of the device of Fig. 2 together with a
programming device according to the invention,

Fig. 6 is a schematic *enlarged scale exploded view of a shape memory alloy*
actuator mechanism according to the invention of the device of Fig. 2,
20

Fig. 7 is a schematic view corresponding to Fig. 6 with the elements of the
shape memory actuator shown in interconnected operative relative positions,

Fig. 8 is a schematic isometric view of a second, more compact embodiment of
25 a disposable insulin dispensing device according to the invention,

Fig. 9 is a schematic, isometric view of the device of Fig. 8 with the top
removed so as to illustrate the co-operating elements of the device,

30 Fig. 10 is a schematic, isometric view of the device of Fig. 8 seen from another
angle than Fig. 9,

Fig. 11 is a schematic exploded view of the device of Figs. 8-10,

Figs. 12a-12c are very schematic views, seen in the direction of the axis of the carpule, of the operation of the drive mechanism of the device of Figs. 8-11 illustrating the interaction of the pawl or ratchet wheel with the spring elements and the shape memory alloy wire,

5

Figs.13-15 are schematic views illustrating a first embodiment of an actuator with a flexible piston rod according to the invention for use in a compact dispensing device according to the invention,

- 10 Fig. 16 is a schematic isometric view illustrating a second embodiment of an actuator with a flexible piston rod according to the invention for use in a compact dispensing device according to the invention, and

Figs. 17-19 are graphs illustrating different insulin dispensing programmes.

15

- Generally speaking, although the device according to the invention is primarily intended for dispensing insulin, it may also be used for dispensing other medicinal substances such as pain-killers, anti-biotics and so on, such that whenever the term insulin is used herein, any other dispensable medicine is
- 20 intended to be covered by the term insulin unless not applicable either by explicit indication or by implicit indication owing to the context wherein the term insulin is employed. Furthermore, it should be noted that when the term carpule is utilized, it is not in any way limited by the WIPO resolutions or any trademark interpretation but is used to denote any cartridge, container, ampoule etc.
- 25 suitable for storing and dispensing medicinal compounds.

- Referring now to Fig. 1, a disposable insulin dispensing device according to the invention, generally referenced by the numeral 1, comprises a water-tight generally cylindrical housing 2 provided with a push button 3 for activating and
- 30 deactivating the device as well as for activating a so-called bolus operation as explained in the following.

The housing further comprises a transparent window 4 for inspecting the operation of the device and apertures 5 for transmission of sound waves as explained in the following.

- 5 At one end of the housing 2 there is provided a stiletto 6 having a sharp needle 7 extending through a catheter 8 connected to a not shown insulin container or carpule inside the housing 2 as explained in the following.

Referring now to Figs. 2-3, the housing 2 is fixedly received in a trough 9 of an
10 adhesive pad 10 made of a combination of a plate 11 of skin-friendly adhesive material, for instance as well known in the field of ostomy pouches, see for instance European patent application no. 0413250 and European patent application no. 0092999, and a relatively compressible portion 10a made of foam material attached to the plate 11. The catheter 8 extends through the
15 planar portion 11 of the pad 10. The push button 3 is protected by the foam material 10a so as to avoid inadvertent operation of the button for instance when the user is asleep.

A slip release film 12 is adhered to the bottom surface of the adhesive plate 11
20 for protecting the adhesive surface of the plate 11 such that the adhesive properties are intact when the pad is to be adhered to the skin of a user of the dispensing device. The release film 12 is provided with a protective hollow projection 13 for receiving the catheter 8 and the needle 7 of the stiletto 6 so that the needle 7 and the catheter 8 are protected by the projection 13 before
25 use of the dispensing device 1. The housing 2 is provided with an end cover 14 on which the catheter 8 is mounted by means of a communication bushing 15 provided with an internal not shown elastomeric mass and a communication passage for communicating the catheter 8 with the interior of the housing 2 as explained in the following in connection with Fig. 4.

30

In use, the user removes the protective release sheet 12 thereby exposing the tip of the needle 7 such that the needle may be inserted subcutaneously at the same time that the adhesive pad 10a, 11 is adhered to the abdominal skin of

the user. When the needle 7 and the catheter 8 have been inserted subcutaneously and the device has been adhered to the skin of the user, the stiletto 6 is removed whereby communication is established between the catheter 8 and the interior of the housing 2 for supplying insulin subcutaneously to the user of the device.

The elastomeric mass in the bushing 15 seals the exit opening of the needle 7 when it is removed such that no insulin may leak through said exit opening but is constrained to flow solely from the carpule to the catheter 8.

10

Referring now to Fig. 4 showing an exploded view of the components of the insulin dispensing device according to the invention, the housing 2 contains a container or a carpule 16 for storing and dispensing insulin. The container or carpule 16 is of a well-known type having a perforatable dispensing projection 17 for receiving a catheter 18 for communicating the interior of the container 16 with the catheter 8 through the communication bushing 15 when the needle 7 has been retracted from said elastomeric mass inside the bushing 15 as explained above.

20 A spindle 19 provided with a piston 20 is received in the container 16 such that axial displacement of the spindle towards the dispensing projection 17 will press insulin through the catheter 18 to the catheter 8. The spindle 19 is rotated and displaced by means of a shape memory alloy actuator described more in detail in the following with reference to Fig. 6.

25

A battery 21 for supplying power to the shape memory actuator is provided adjacent an end cover 22 of the housing 2.

The shape memory actuator comprises a pawl or ratchet wheel 23, a guide bushing 24, a spring wheel 25 and a shape memory wire 26. The operation of the shape memory actuator will be described more in detail in the following with reference to Figs. 6 and 7.

A printed circuit board 27 is provided for controlling the function of the dispensing device and the various operational steps thereof as described in the following.

- 5 Finally a combined microphone/loudspeaker 28 is arranged inside the housing 2 adjacent the apertures 5 for receiving and emitting sound waves for the purposes described below.

Referring now to Fig. 5, a programming device or controller 29 having
10 programming keys 30 and a display 31 is shown proximate the dispensing device for communicating with a not shown receiver/transmitter arranged inside the housing 2. The communication may take place by infra red signals or other suitable signals transmitted from and to an opening 32 leading to a transmitter/receiver inside the controller 29 to and from, respectively an
15 opening 33 (see Fig. 2) in the end cover 22 of the housing 2 leading to said not shown transmitter/receiver inside the housing 2.

Referring now to Figs. 6 and 7, the spindle 19 is displaced axially in the direction of the arrow R1 by counter-clockwise rotation of the pawl wheel 23 in
20 the direction of the R2 whereby the thread 36 meshing with the internal thread 37 results in said axial displacement whereby the piston 20 is displaced further into the carpule 16 to dispense insulin through the catheter 18 to the catheter 8 (Fig. 4).

- 25 Rotation of the pawl wheel 23 is accomplished by means of the shape memory alloy (for instance Nitinol) wire 26 attached to electrically conductive rods 38 and 39 that are fixed in recesses 40 and 41, respectively, in the electrically non-conductive guide bushing 24 and the electrically conductive spring wheel 25, respectively.

30

The recess 40 is provided with not shown electrical contacts for electrically connecting the rod 39 to the battery 21 for supplying electrical current to the

SMA wire 26 to heat it in a manner and sequence controlled by the programme elements in the print board 27.

5 The spring wheel 25 has U-shaped spring arms 44 and 45 for exerting a spring force on the ends 46 and 47 thereof, respectively, in a direction towards the centre of the pawl wheel 23 such that the ends 46 and 47 are constantly biased to enter into engagement with the teeth of the pawl wheel 23.

10 The stop pins 42 and 43 are electrically connected to the print board 27 for emitting an electrical signal thereto when the spring wheel arm 48 contacts said stop pins.

The rod 38 is as mentioned above electrically connected to the power source such that an electrical current may be passed through the rod 38, the wire 26, 15 the rod 39, the loop recess 41 and the spring wheel 25 to heat the wire 26 to cause the wire to contract and rotate the pawl wheel the distance of one tooth in the direction of arrow R2 by means of the arm end 46 engaging a tooth of the wheel until the arm 48 contacts the stop pin 42 that emits a signal to the control print board 27 whereby the current through the wire 26 is interrupted and the 20 SMA wire 26 cools off and expands.

The other arm end 47 engages a tooth of the wheel 23 as a pawl and prevents the wheel 23 from rotating clock-wise. The spring effect of the spring wheel 25 in the tangential direction causes the arm 42 to move back into contact with the 25 stop pin 43 thereby tightening the expanded SMA wire 26.

The signals from the stop pins 42 and 43 are also utilized to indicate correct functioning of the pump and as an indication of the number of doses administered through the catheter 8.

30

Referring now to Figs 8-12, a second, more compact, embodiment of a medicine pump 51 according to the invention comprises a housing upper portion 52 and a housing lower portion 53, the upper portion 52 having audio

apertures 54 for allowing audio signals to travel relatively unencumbered through the wall of the upper portion 52 from and to an audio element 54a, a bolus button aperture 55 for allowing depression of a bolus button 56 and an inspection aperture 57 covered by a transparent element 57a for allowing
5 monitoring of the contents of an insulin carpule 58 provided inside the housing.

The lower housing portion 53 is adhered to an adhesive pad 59 covered by a release sheet with a needle protection projection or indentation 61 very similar to the corresponding elements of the embodiment of Figs.1-4. The carpule 58
10 co-operates with a catheter/stiletto assembly 62 in the same manner as described in connection with the embodiment of Figs.1-4.

The embodiment of Figs. 8-12 is very similar in construction and in operation to the embodiment of Figs. 1-4 with the exception of the rigid rectilinear spindle or
15 piston rod 19 being substituted by a flexible piston rod 63 according to the invention and the design of the shape memory alloy wire actuator as will be described in the following.

A piston 64 corresponding to piston 20 of Fig. 4 is attached to one end of a
20 flexible piston rod 63 constituted by a series of elements 65 interconnected by hinge means 66 (see Figs. 13-15) and arranged for movement between two guide walls 63a and 63b. The piston 64 abuts a displaceable wall or piston 66 of the carpule 58 such that axial displacement of the piston 64 will press insulin out of the carpule 58 into the catheter assembly 62.

25

The elements 65 are integral with each other by means of hinges 66 which allow adjacent elements to pivot relative to one another from the position abutting one another shown in Fig. 14a wherein the elements 65 together form a rectilinear piston rod with abutment surfaces 65a and hinges 66 affording
30 rigidity and thus rendering the piston rod 63 capable of exerting a pressure on the piston 66 of the carpule without laterally deflecting, to the position shown in Fig. 14b wherein the elements are pivoted away from one another so as to allow the curvature of the piston rod 63 which allows the compact configuration of the

device with the initially major part of the piston rod extending along the length of the carpule 68.

The material of the flexible piston rod 63 is any suitable mouldable material, but
5 it is preferred that the material is a plastics material such as Nylon or POM because of cost and re-cycling issues.

Each element 65 is provided with exterior threads 67 on two opposed portions 69 and 70 of the elements having a circular cylindrical configuration for allowing
10 an internal thread 71 of a pawl or ratchet wheel 72 (Fig.12) to mesh therewith such that rotation of the pawl wheel 72 will displace the piston rod 63 into the carpule 58. At least the side of the elements 65 coinciding with the hinges 66 is flat to allow practical moulding of the hinge. The flat side or flat opposed sides also allows preventing rotation of the piston rod 63 around its axis when being
15 axially displaced by the internal thread 71 of the pawl wheel 72

The pawl wheel 72 is rotated by a shape memory alloy actuator comprising a wire 73 of a shape memory alloy such as Nitinol, one end of which is attached to a rivet 74 and the other end of which is attached to the free end of an
20 actuator spring rod 75 by means of a crimp 76. The wire 73 extends around a pin 73a for change of direction. The free end of the actuator spring rod 75 is located such that it meshes with the teeth of the pawl wheel 72 and is biased by the spring force of the rod to exert a spring force in the tangential direction (arrow R1) and in the radial direction (arrow R2). Two end stop pins
25 77 and 78 limit the tangential movement of the actuator spring rod end 75.

A pawl spring rod 79 is located such that the end thereof meshes with the teeth of the pawl wheel 72 and is biased to exert a spring force in the radial direction (arrow R3). This end of the pawl spring rod 79 is constrained to substantially
30 only move in the radial direction by two stop pins 80.

A battery 81 supplies power to the ends of the nitinol wire 73 for heating it so as to cause it to contract. The battery 81 is connected to the rivet 74 and the crimp

76 through a flexible printed circuit film on which is incorporated the control circuits necessary for any programmed sequence of heating and cooling of the wire 73 as well as any other electronically controlled functions of the device.

- 5 Rotation of the pawl wheel 72 in the counter clock-wise direction of the arrow R4 is brought about as illustrated in Figs. 12a-12c. In Fig. 12a the wire 73 is cool and expanded so that the actuator spring rod end 75 is in its rightmost position abutting end stop pin 78. The pawl spring end 79 locks the pawl wheel 72 against clock-wise rotation.

10

In Fig. 12b the nitinol wire 73 has been heated and has contracted thereby pulling the actuator rod end 75 to the left against the spring forces R1 and R2 until it abuts the end stop pin 77.

- 15 In Fig. 12c the nitinol wire 73 has been cooled and the actuator spring rod end 75 is rotating the wheel 72 counter clock-wise until abutting end stop pin 78 again while the pawl rod end is ratcheting against the spring force R3. Hereby, the pawl wheel has been rotated the *peripheral distance of one tooth thereof*.

- 20 As the pawl wheel rotates, the internal thread 71 of the wheel meshing with the threads 67 of the flexible piston rod elements 65 displaces the piston rod 63 into the carpule 58 for dispensing insulin through the catheter 62.

- 25 The end stop pins 77 and 78 are electrically connected to the flexible print board film 82 so that monitoring of the correct function of the actuator may take place by registering electrical contact between the end stop pins 77, 78 and the spring rod end 75 which indicates correct functioning of the actuator.

- 30 The flexible piston rod 63 could also be displaced by means of another actuator, for instance such as described in connection with the embodiment of Figs. 1-4.

Referring now to Fig.16, a carpule 58 identical to the one described in connection with Figs. 8-11 is located adjacent an actuator generally referenced by the numeral 90 with a piston 91 of the actuator abutting the not visible piston 66 of the carpule.

5

The piston 91 is attached to the end of a steel strip 92 having an arcuate cross section taken at right angles to the longitudinal direction of the strip. This arcuate shape entails a rigidity of the strip 92 against lateral deflection such that the strip can transmit pressure forces to the piston 91 without collapsing
10 because of lateral deflection.

A row of evenly spaced elongate apertures 93 are provided in the strip 92 for receiving ribs 94 of a roller 95 having a gear 96 meshing with a worm gear 97. The worm gear is actuated by an actuator that may be similar to the shape
15 memory alloy actuators of Figs 6-7 or 8-12.

By rotating the worm gear 97 the gear 96 and roller 95 are rotated whereby the ribs 94 received in the slits 93 unwind the strip 92 from the roll and displace it into the carpule whereby the piston 91 displaces the carpule piston and
20 dispenses the insulin from the carpule 58 that is located in the dispensing device in the same manner as the carpule 58 of Figs. 8-12.

A medicine dispensing device or insulin pump according to the invention may function in several different manners depending on the design and
25 programming of the various control elements of the circuit board 27:

1. Stand alone pump with constant flow:

The pump functions as a constant flow pump and may be designed for different flow rates, for instance 20 units/24 hours, 30 units/24 hours, etc. By depressing
30 the bolus button 3 and holding it down, the pumping programme is initiated and by again pressing the button 3 down and holding it, the pumping programme is terminated while a short duration pressure on the bolus button 3 activates a bolus additional dosage of insulin of a certain magnitude.

Fig. 17 illustrates a possible programming of this type with the line 100 indicating a constant flow corresponding to 50 units/24hr with a flow pause indicated at 101 between 20 and 21 hours after start. Bolus extra dosages are indicated at 102 and 103. Other flow rates are indicated with broken line graphs.

2. Stand alone pump with varying flow:

A timing device is incorporated in the print board 27 so that a standard programme controls the flow dispensed by the pump during recurring 24 hour periods. The pre-programmed operating instructions may for example result in a lower dosage at night than during the day and an extra dosage at mealtimes.

Fig. 18 illustrates a possible programming of this type with the graph 104 indicating night-time dosage 105, day-time dosage 106, meal-time dosage 107, dosage pause 108 and bolus 109. Other dosage programmes are indicated in broken lines.

3. Programmable pump type 1:

The pump is not provided with a predetermined programme, but is provided with a programmable unit in the print board 27 and can be programmed by the user or a doctor by means of a controller 29. The programming must be able to take place through the packing material in which the dispensing device is supplied so that the user can transport the device in a sterilised packaging on vacations or the like without having to carry the controller along. The controller is a dedicated unit that for instance via a USB plug can be connected to a PC or it can be provided with cellular telephone capability for transmission of data. The controller can thus be programmed by a doctor or a user and be used for programming of the functioning of all subsequently used disposable dispensing devices.

4. Programmable pump type 2:

This pump functions in the same manner as programmable pump type 1, but the controller is a palm pilot or a laptop PC. This gives the additional advantage that the user may input health information and glucose level measurement results directly into the controller or programming unit and thus communicate such information to the doctor who may use this information when deciding whether the programming function of the controller or the programming unit is to be altered for subsequently used disposable dispensing devices.

5. Programmable pump with audio input and output:

By providing the dispensing device with the microphone/loudspeaker 28 and a suitable recording/play-back chip in the printed circuit 27, short messages may be recorded by the dispensing device, and the short messages may be emitted by the device upon suitable manipulation of the bolus push button 3 or a separate recording button (not shown) mounted on the housing 2.

By means of this audio capability the user may record verbally formulated information regarding *glucose levels*, *meal composition*, *exercise*, etc. A timer may record the timing of each recorded message. A doctor may then use these recorded messages together with information about number and timing of bolus dosages, pumping stops and the programme utilised for the dispensing of the insulin so as to evaluate the treatment and decide upon any changes in the programming and instructions to the patient which may be recorded by the doctor via a mobile telephone or the like such that messages are automatically delivered to the user at predetermined times. Such a message could for example be 'remember to measure your glucose level' (message programme to be delivered by the dispensing device to the user each morning at 8 o'clock) and so on.

Furthermore, standard instructions can be included in the programming circuit so that the pump may deliver verbal messages to the user instead of audio signals such as beep sounds. The message could for instance be: 'Pump is stopped' or 'This is your third bolus in a row and you have taken a total of eight

bolus dosages today' or 'The pump will be empty in two hours' and so on. Generally speaking, the audio capability described above will render the dispensing device provided with such capability much more user-friendly, especially for users initiating a treatment or not very disciplined as regards
5 compliance.

6. Closed loop re-programmable pump:

Either the controller or the computing unit mounted in the printed circuit 27 may be programmed to react to information regarding actual glucose blood level
10 inputted by the user perhaps together with other information, such as data regarding the timing and constitution of the last meal, to alter the programme of the dispensing flow or dosage to take into consideration this information such that the dispensing device to a certain extent constitutes a closed loop, fuzzy logic, semi-automatic self re-programming insulin dispensing device.

15

Referring now to Fig. 19, the graph illustrates a dispensing programme which may be used for the pumps type 3-6 where the flow varies according to time and/or to input data.

20

The programming controller 29 may be a mobile wire-less communication device such as a cellular telephone communicating with the dispensing device
25 by audio signals transmitted to and received from the transmitter/receiver 28. The transmissions should be preceded and terminated by an identification code to avoid disruption of the programming of the device by extraneous audio signals. Other signal identification or protection procedures such as encryption may be utilized. The audio signals may be converted to controlling signals for
30 altering the programming of the re-programmable computing unit mounted in the circuit board 27.

Signal conversion means may be provided for converting the audio signals received by the receiver into input signals for the computing means and for converting output signals from the computing means into audio signals for being transmitted by the loudspeaker.

5

Wire-less so-called SMS signals may also be utilized for transferring information between a wire-less mobile communications unit and the dispensing device, for instance by means of IR signals or so-called Bluetooth communication technology.

10

Although the basic concept of the invention is that the entire device is disposable, a variation may be that the receiver/transmitter unit 28 with recording and play back components and corresponding battery and perhaps circuit board with computing means is reusable and may be releasably received

15 in a holder provided on the disposable portion of the device.

CLAIMS

1. A disposable, wearable, self-contained medicine, particularly insulin
5 dispensing device comprising:
- a housing,
 - an insulin source in said housing,
 - a pump means in said housing and adapted for pumping insulin from said
insulin source to a catheter for injection of said insulin in a user of the device
10 and, said catheter being associated with said housing and projecting generally
perpendicularly to a generally planar surface of said housing intended for
abutting a skin surface of a user of the device,
 - an adhesive layer provided on said planar surface for adhering said planar
surface to said skin surface, and
 - 15 - a removable release sheet covering said adhesive layer for protecting said
adhesive layer prior to use of said dispensing device, said release sheet being
provided with catheter protection means to enclose and protect an end portion
of said catheter such that removal of said release sheet for exposing said
adhesive layer exposes said end portion.
- 20
2. A dispensing device according to claim 1, wherein said catheter protection
means comprises an indentation in said release sheet.
3. A disposable, wearable, self-contained medicine, particularly insulin
25 dispensing device comprising:
- a housing,
 - an insulin source in said housing,
 - a pump means in said housing and adapted for pumping insulin from said
insulin source to a catheter for injection of said insulin in a user of the device
30 and, said catheter being associated with said housing and projecting generally
perpendicularly to a generally planar surface of said housing intended for
abutting a skin surface of a user of the device,

- an adhesive layer provided on said planar surface for adhering said planar surface to said skin surface,
 - a combined microphone and loudspeaker associated with said housing, preferably arranged inside said housing,
 - 5 - recording and play back means connected to said combined microphone and loudspeaker and associated with said housing, preferably arranged inside said housing, such that verbal messages may be recorded and played back by said dispensing device.
- 10 4. A disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising:
- a housing,
 - an insulin source in said housing,
 - a pump means in said housing and adapted for pumping insulin from said
 - 15 insulin source to a catheter for injection of said insulin in a user of the device, and
 - an actuator for said pump means, said actuator comprising a shape memory alloy wire.
- 20 5. A dispensing device according to claim 4, wherein said actuator further comprises a ratchet gear or pawl wheel, a pawl adapted for co-operating with said pawl wheel and connected to one end of said shape memory alloy wire and a spring means connected to said pawl, the connections between said pawl and said wire and said pawl and said spring means being such that
- 25 contraction of said wire rotates said pawl wheel against the spring force of said spring means.
6. A disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising:
- 30 - a housing,
- an insulin source in said housing,
 - a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device,

- an actuator for said pump means, preferably an actuator comprising a shape memory alloy wire, and
- controlling means for controlling the operation of said actuator according to a programme.

5

7. A dispensing device according to claim 6, wherein said programme consists in a sequence of a certain amount of actuations of said actuator per 24 hours time periods.

10 8. A dispensing device according to claim 6 and further comprising a timing means connected to said controlling means, wherein said programme consists in a sequence of actuations of said actuator that varies according to the time of day.

15 9. A dispensing device according to claim 6 and further comprising

- a timing means connected to said controlling means,
- an input device for inputting data to said controlling means, said controlling means being programmable by means of said data.

20 10. A dispensing device according to claim 9, wherein the programme of said controlling means comprises algorithms for automatically altering the sequence of actuations of said actuator according to input of data relative to actual glucose level in the blood of the use of the device and/or intake of nutrients by said user.

25

11. A dispensing device according to any of the claims 3-10 and further comprising:

- a catheter for injection of said insulin in a user of the device and, said catheter being associated with said housing and projecting generally perpendicularly to
- 30 a generally planar surface of said housing intended for abutting a skin surface of a user of the device,
- an adhesive layer provided on said planar surface for adhering said planar surface to said skin surface, and

- a removable release sheet covering said adhesive layer for protecting said adhesive layer prior to use of said dispensing device, said release sheet being provided with catheter protection means to enclose and protect an end portion of said catheter such that removal of said release sheet for exposing said
5 adhesive layer exposes said end portion.

12. A dispensing device according to claim 11, wherein said catheter protection means comprises an indentation in said release sheet.

10 13. A dispensing device according to any of the claims 1-2 and 4-10 and further comprising:

- a combined microphone and loudspeaker associated with said housing, preferably arranged inside said housing, and
- recording and play back means connected to said combined microphone and
15 loudspeaker and associated with said housing, preferably arranged inside said housing, such that verbal messages may be recorded and played back by said dispensing device.

14. A dispensing device according to any of the claims 4-5 and further
20 comprising controlling means for controlling the operation of said actuator according to a programme.

15. A dispensing device according to claim 14, wherein said programme consists in a sequence of a certain amount of actuations of said actuator per 24
25 hours time periods.

16. A dispensing device according to claim 14 and further comprising a timing means connected to said controlling means, wherein said programme consists in a sequence of actuations of said actuator that varies according to the time of
30 day.

17. A dispensing device according to claim 14 and further comprising
- a timing means connected to said controlling means,

- an input device for inputting data to said controlling means, said controlling means being programmable by means of said data.

18. A dispensing device according to claim 17, wherein the programme of said
5 controlling means comprises algorithms for automatically altering the sequence of actuations of said actuator according to input of data relative to actual glucose level in the blood of the use of the device and/or intake of nutrients by said user.

10 19. A dispensing device according to any of the preceding claims, wherein the pump means comprises a piston rod for displacing a piston in a cylindrical container of said medicine to be dispensed and an actuator for displacing said piston rod, wherein said piston rod is configured such that the portion of said piston rod between said actuator and said piston is rectilinear and rest of said
15 piston rod is arcuate.

20. A dispensing device according to claim 19, wherein the piston rod comprises elements arranged in a row and interconnected by hinge elements.

20 21. A dispensing device according to claim 19, wherein each element is provided with a surface spaced from said hinge element and configured to abut a corresponding surface of an adjacent element when said piston rod is rectilinear.

25 22. A dispensing device according to claim 20 or 21, wherein said elements are provided with screw threads on the outer surface thereof for co-operating with corresponding screw threads of the actuator.

23. A dispensing device according to claim 19, wherein the piston rod
30 comprises a strip having an arcuate cross section taken transverse to the longitudinal direction of said strip.

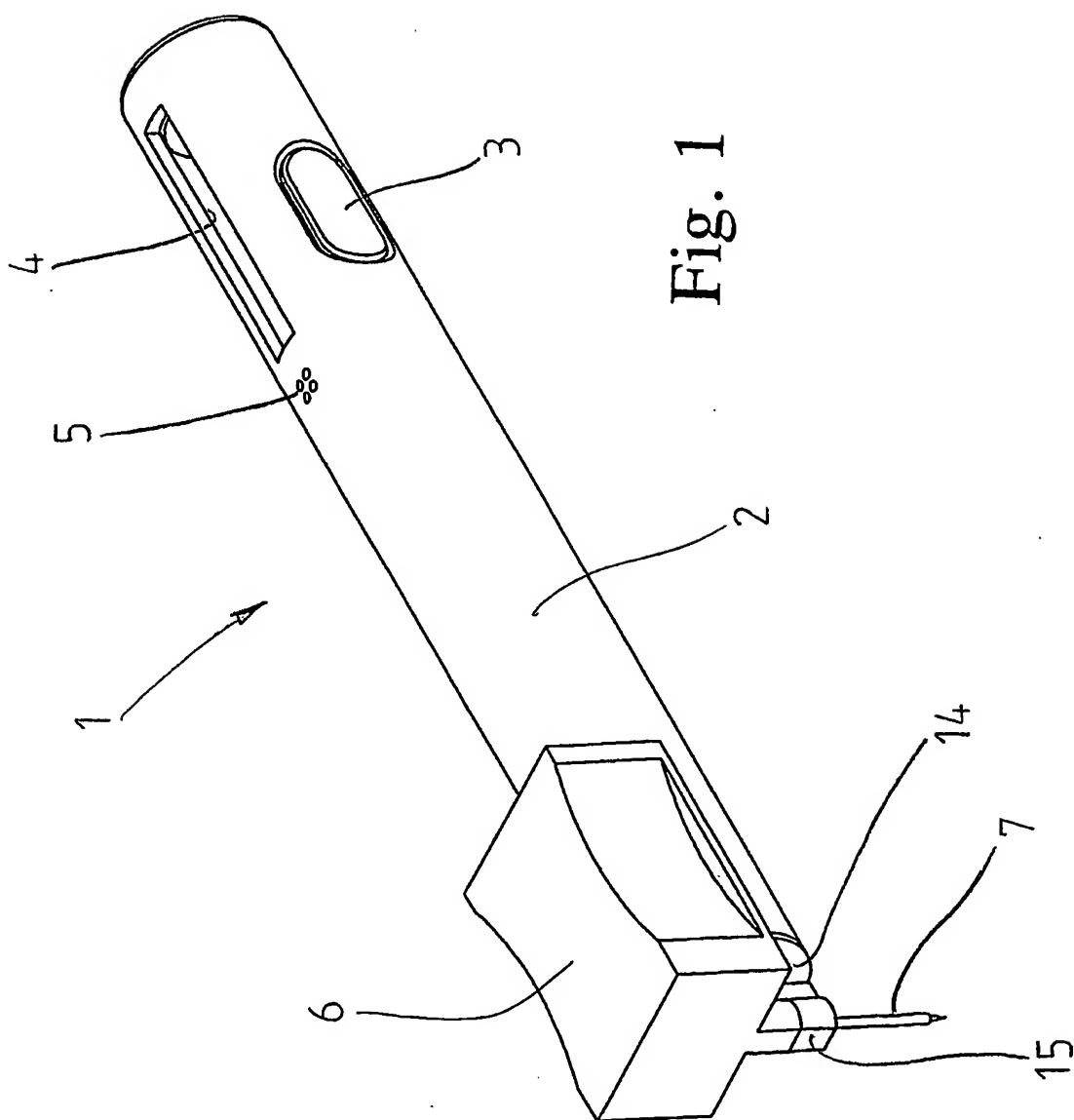
24. A dispensing device according to claim 23, wherein said strip is rectilinear between said actuator and said piston while the rest of the strip is wound into a roll.
- 5 25. A dispensing device according to claim 23 or 24, wherein said strip is provided with apertures, preferably transversely extending slits, evenly spaced along the length thereof for receiving corresponding projections of said actuator.
- 10 26. A combination of a dispensing device according to any of the claims 6-25 and a programming controller, said dispensing device and said programming controller comprising co-operating transmission and/or receiving means for mutual communication of data.
- 15 27. A combination according to claim 26, wherein said programming controller is a cellular telephone or a personal computer or a laptop computer or a hand held computer.
28. A method of controlling the operation of a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising:
- 20 - a housing,
- an insulin source in said housing,
- a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device,
25 - an actuator for said pump means, preferably an actuator comprising a shape memory alloy wire, and
- controlling means for controlling the operation of said actuator according to a programme,
said method comprising the steps of:
- 30 - providing said controlling means with data for generating and/or amending said programme prior to and/or after initiation of use of said dispensing device.

29. A method of controlling the operation of a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising
- a housing,
 - an insulin source in said housing,
 - 5 - a pump means in said housing and adapted for pumping insulin from said insulin source to a catheter for injection of said insulin in a user of the device and, said catheter being associated with said housing and projecting generally perpendicularly to a generally planar surface of said housing intended for abutting a skin surface of a user of the device,
 - 10 - an adhesive layer provided on said planar surface for adhering said planar surface to said skin surface,
 - a combined microphone and loudspeaker associated with said housing, preferably arranged inside said housing,
 - recording and play back means connected to said combined microphone and
 - 15 loudspeaker and associated with said housing, preferably arranged inside said housing, such that verbal messages may be recorded and played back by said dispensing device, an
 - manual operating means for manually controlling the operation of said dispensing device
 - 20 said method comprising the steps of:
 - recording verbal instructions in said recording means for instructing the user of the device in the operation of said dispensing device, and
 - playing back said verbal instructions.
- 25 30. A method of controlling the operation of a disposable, wearable, self-contained medicine, particularly insulin dispensing device comprising:
- a housing,
 - an insulin source in said housing,
 - a pump means in said housing and adapted for pumping insulin from said
 - 30 insulin source to a catheter for injection of said insulin in a user of the device and, said catheter being associated with said housing and projecting generally perpendicularly to a generally planar surface of said housing intended for abutting a skin surface of a user of the device,

- an adhesive layer provided on said planar surface for adhering said planar surface to said skin surface,
 - a combined microphone and loudspeaker associated with said housing, preferably arranged inside said housing,
 - 5 - a programmable computing means associated with said housing, preferably arranged inside said housing, and
 - signal conversion means connected to said combined microphone and loudspeaker and associated with said housing, preferably arranged inside said housing, and adapted for converting received audio signals into input signals
 - 10 for said computing means and for converting output signals from said computing means to audio signals,
- said method comprising one or more of the steps of:
- transmitting audio signals to said microphone for controlling the operation of said dispensing device,
 - 15 - receiving audio signals from said loudspeaker for evaluating the operation of said dispensing device.

31. A method of controlling the operation of a dispensing device according to any of the claims 6-25, said method comprising the step of providing said

20 controlling means with data for generating and/or amending said programme prior to and/or after initiation of use of said dispensing device.



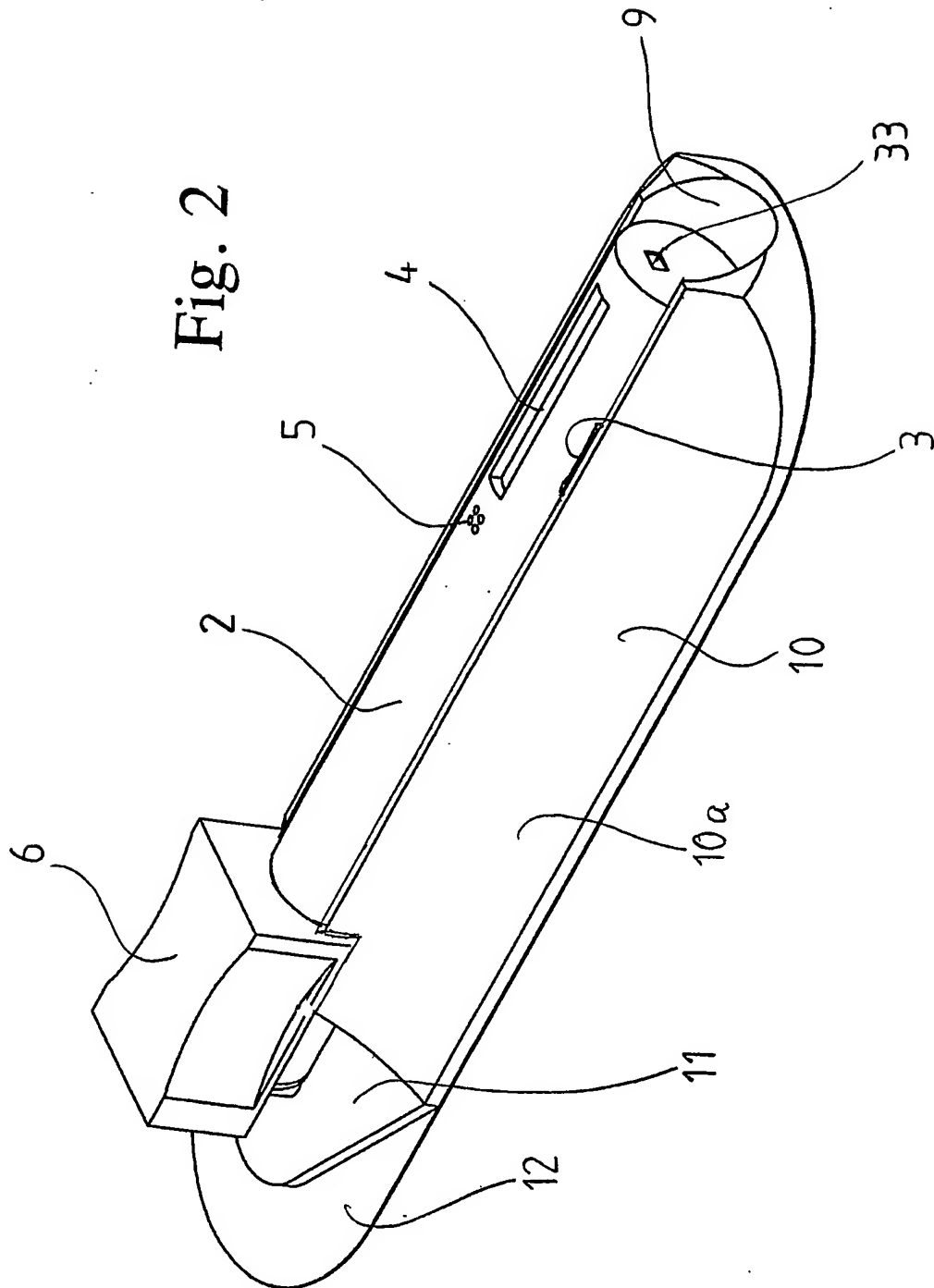
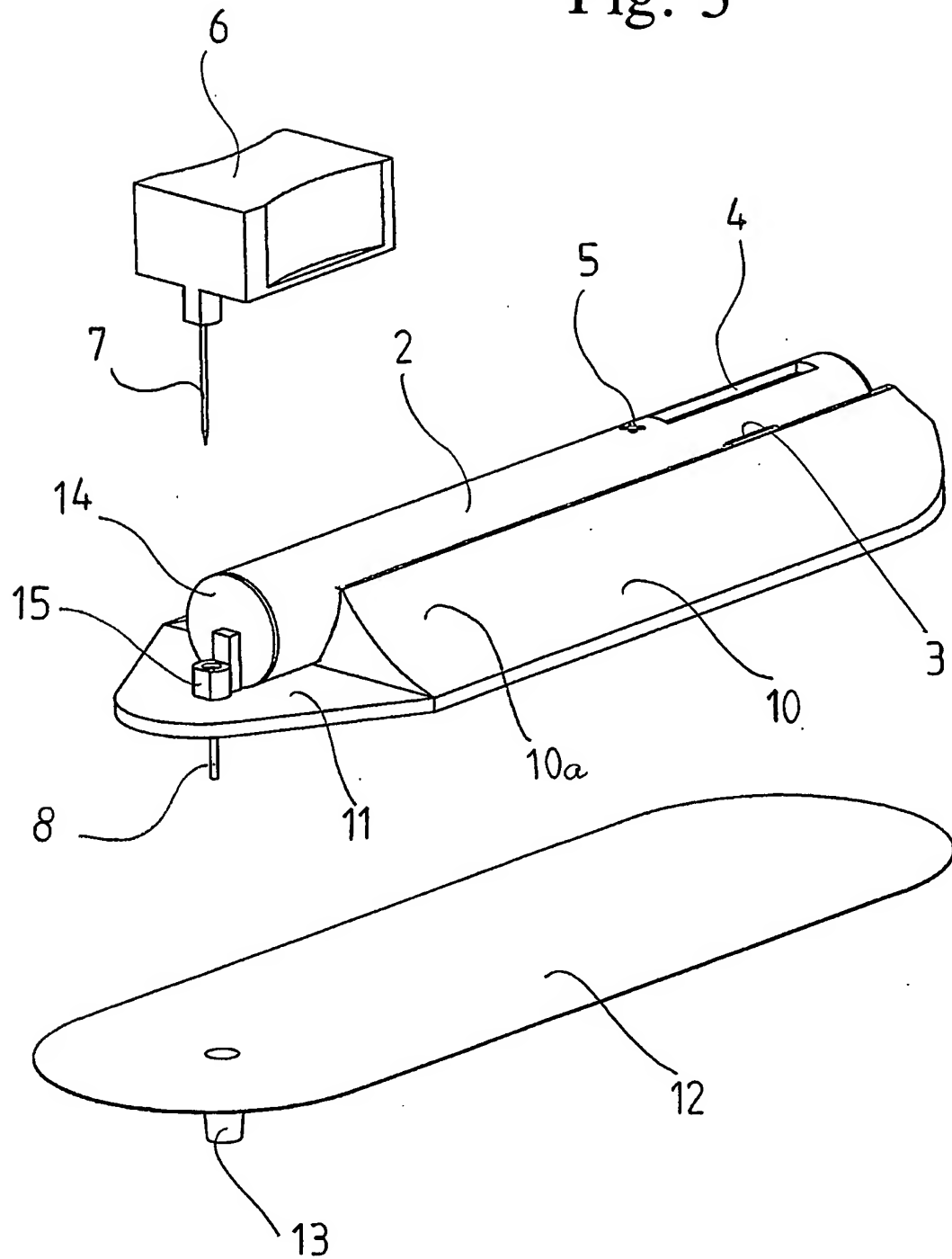


Fig. 3



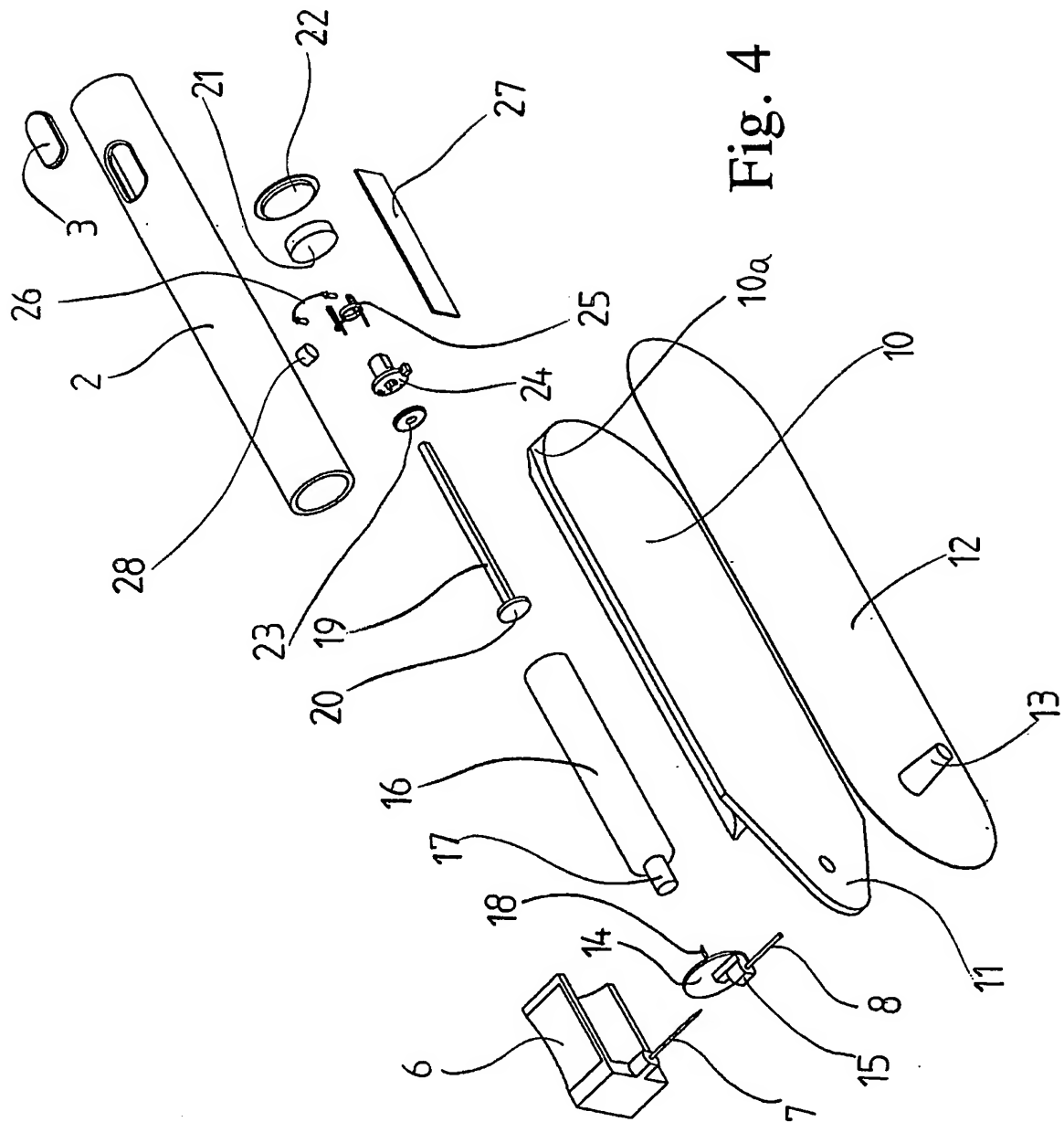
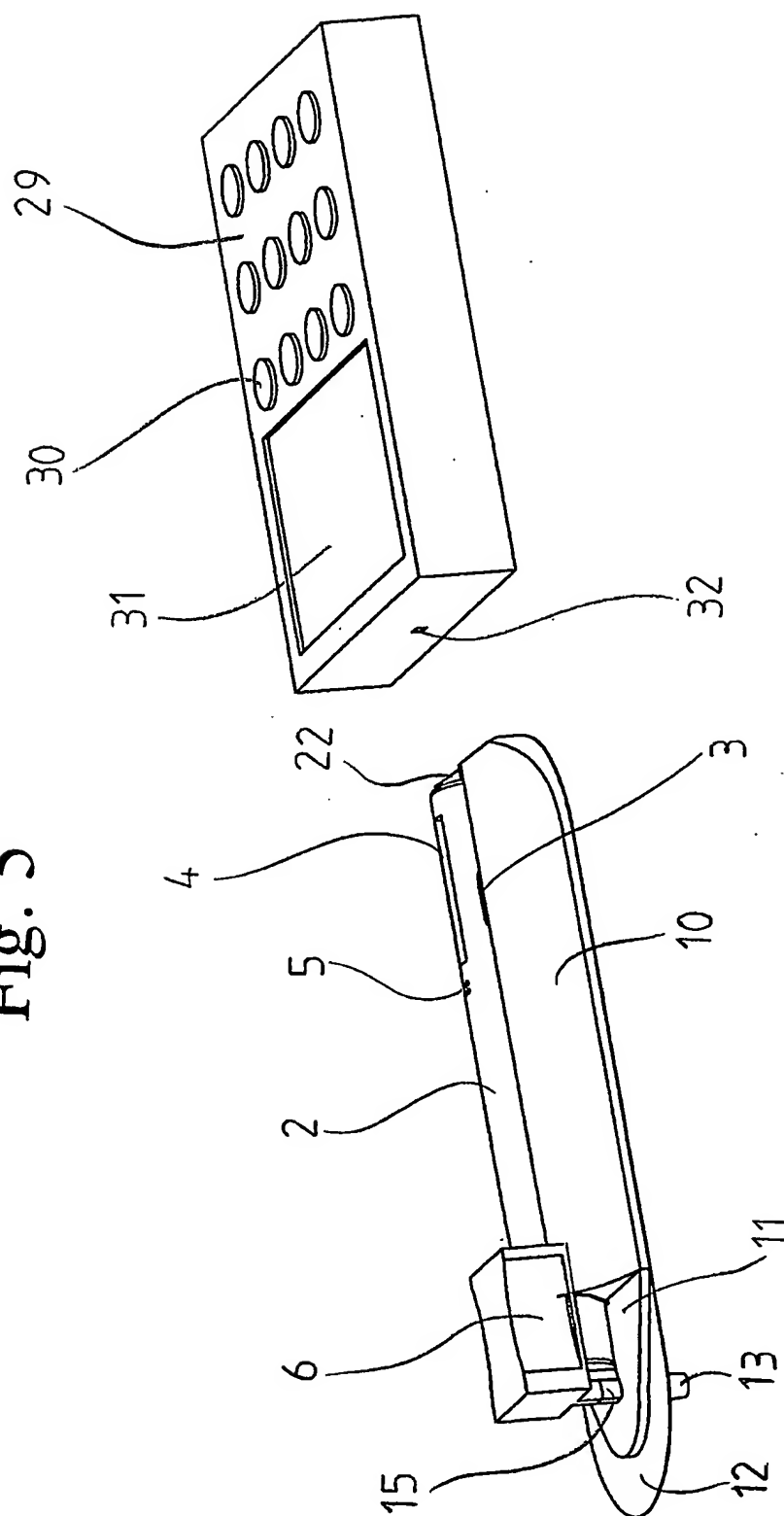
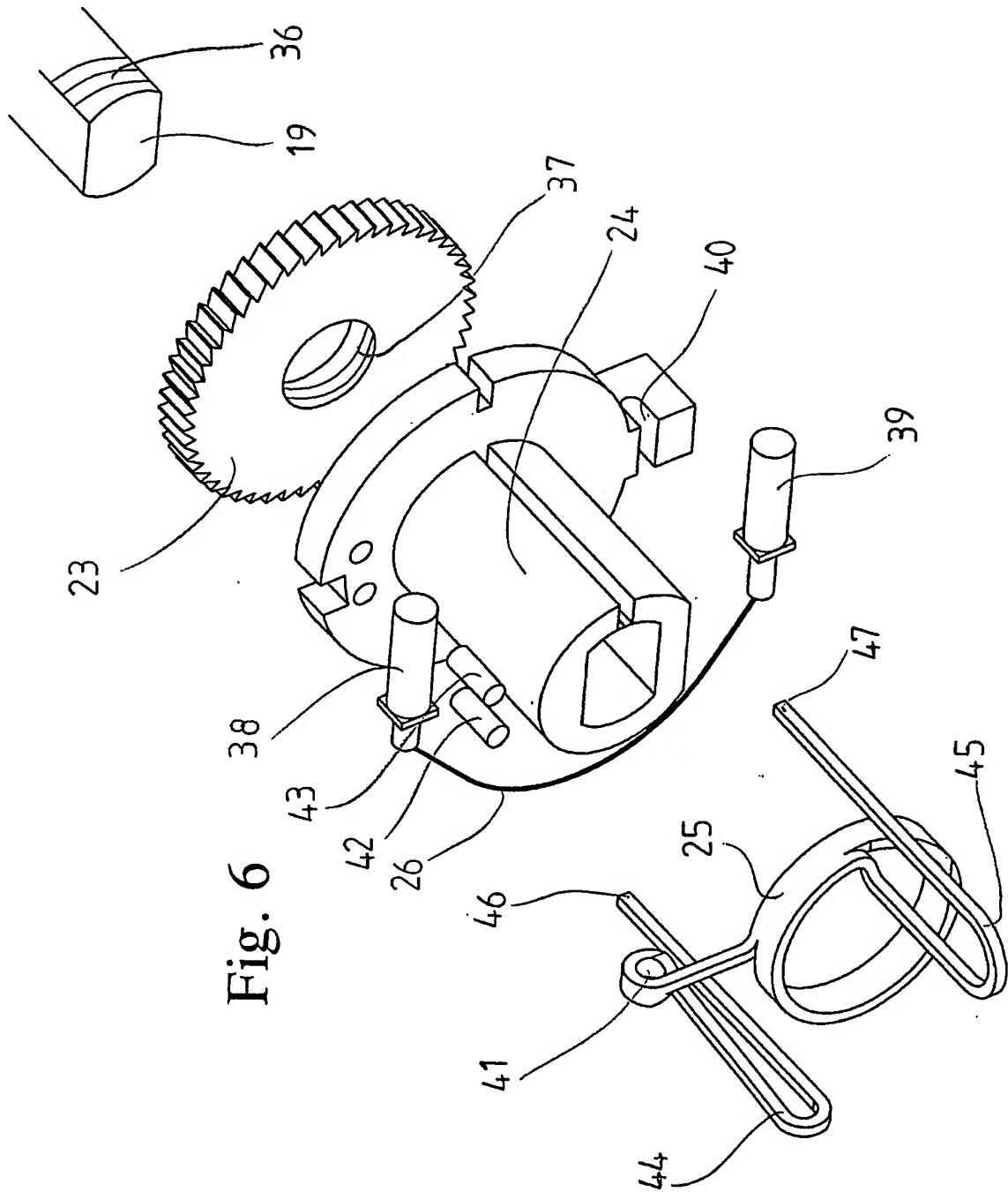


Fig. 4

Fig. 5





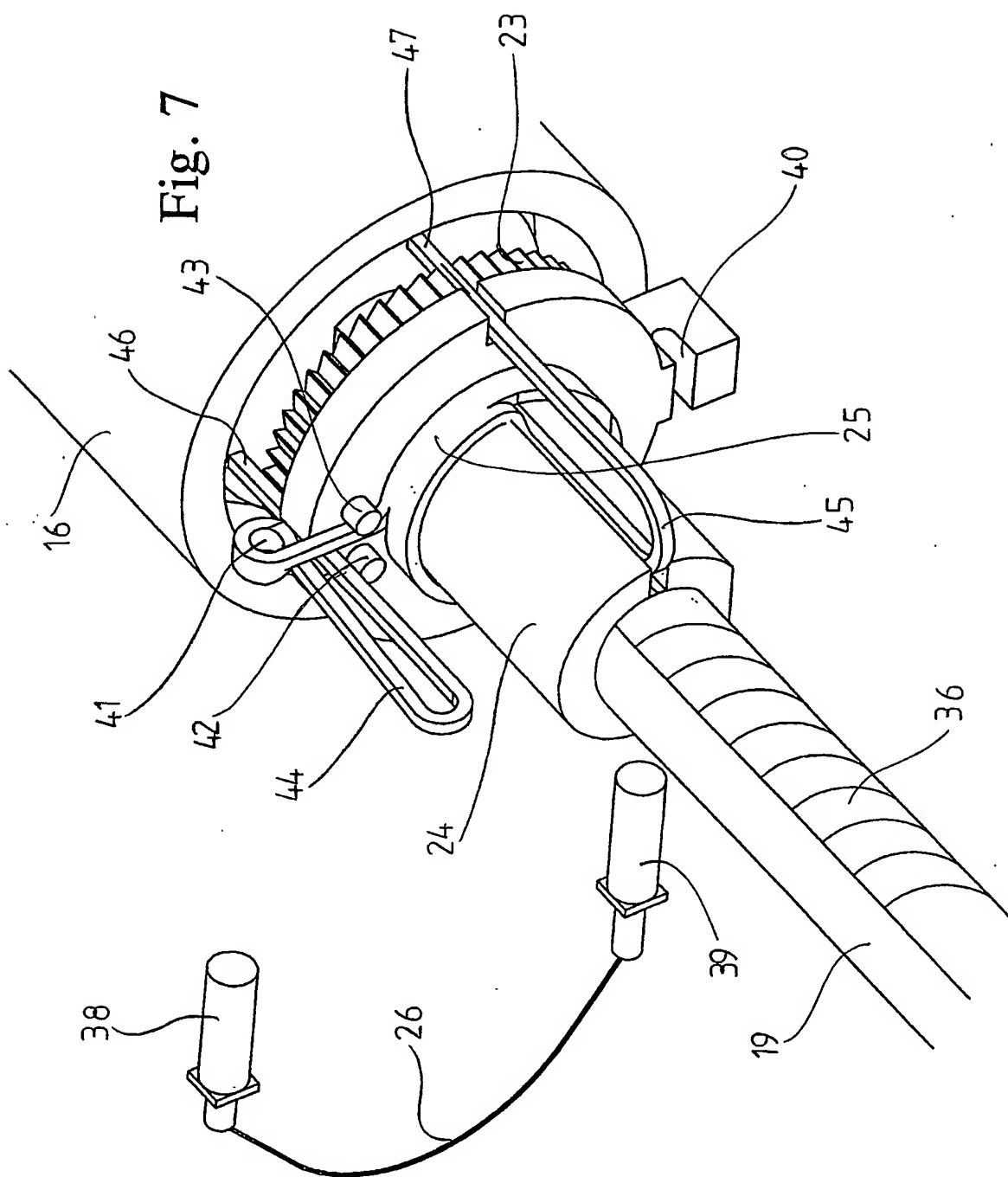


Fig. 8

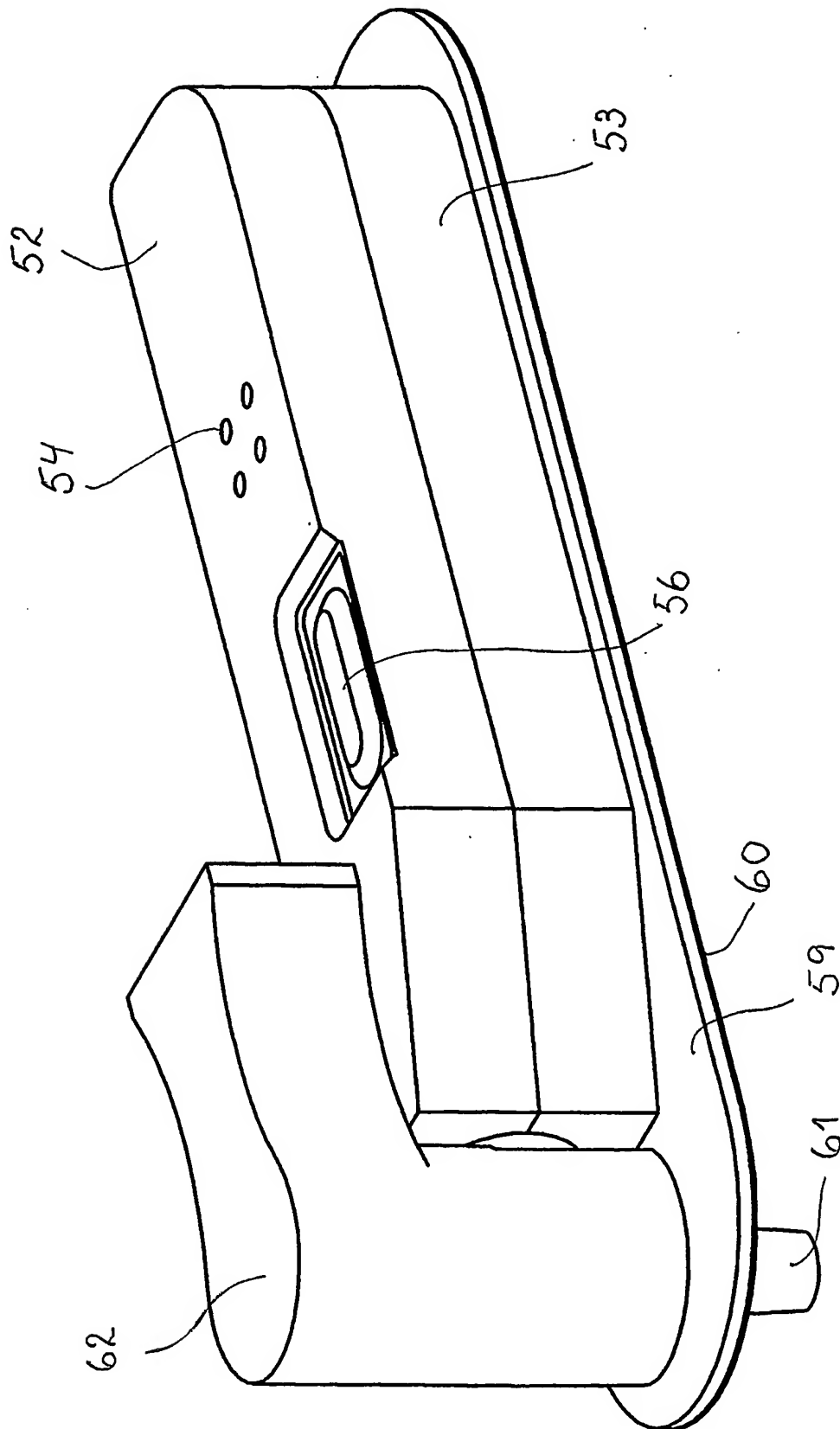
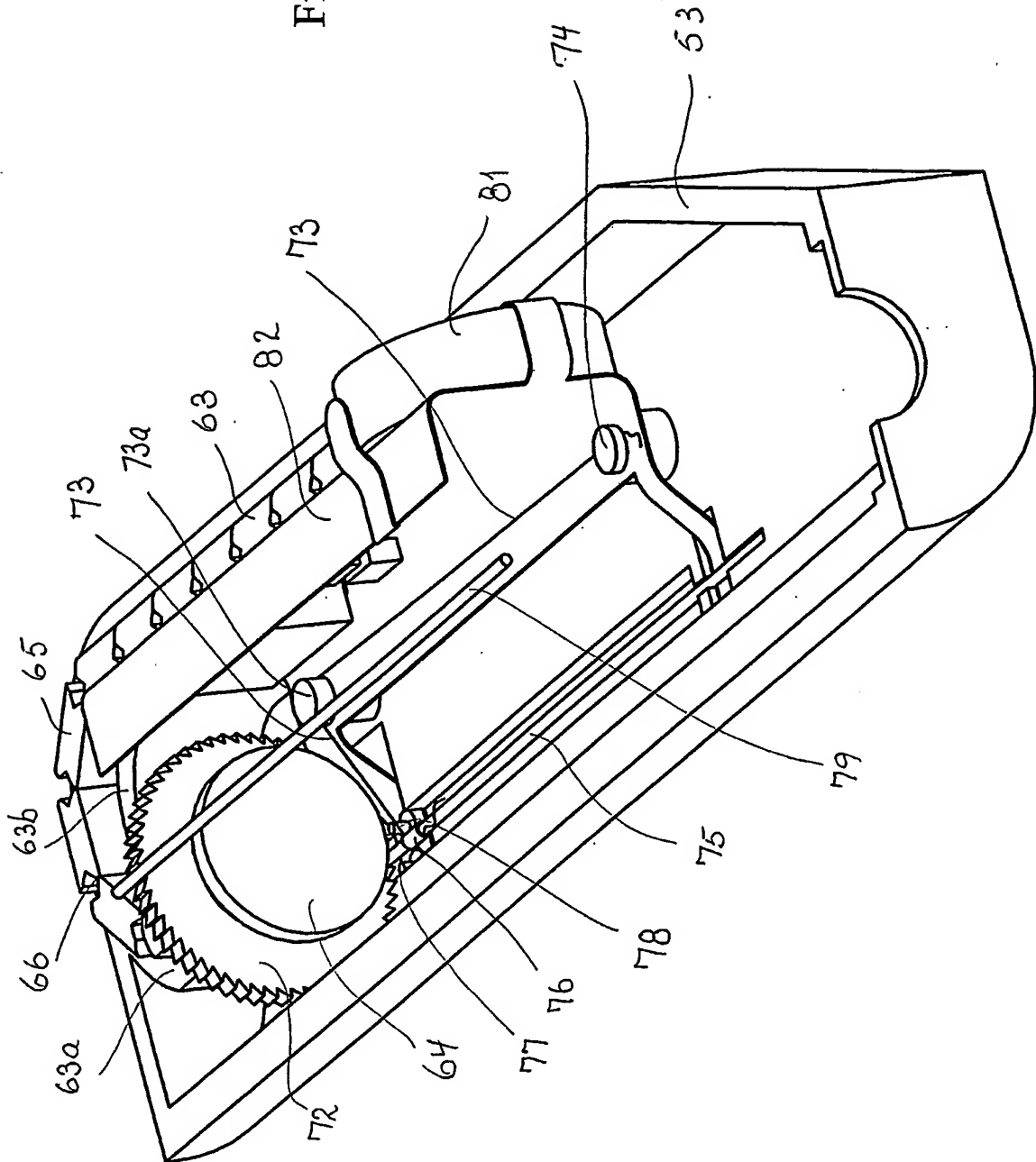


Fig. 9



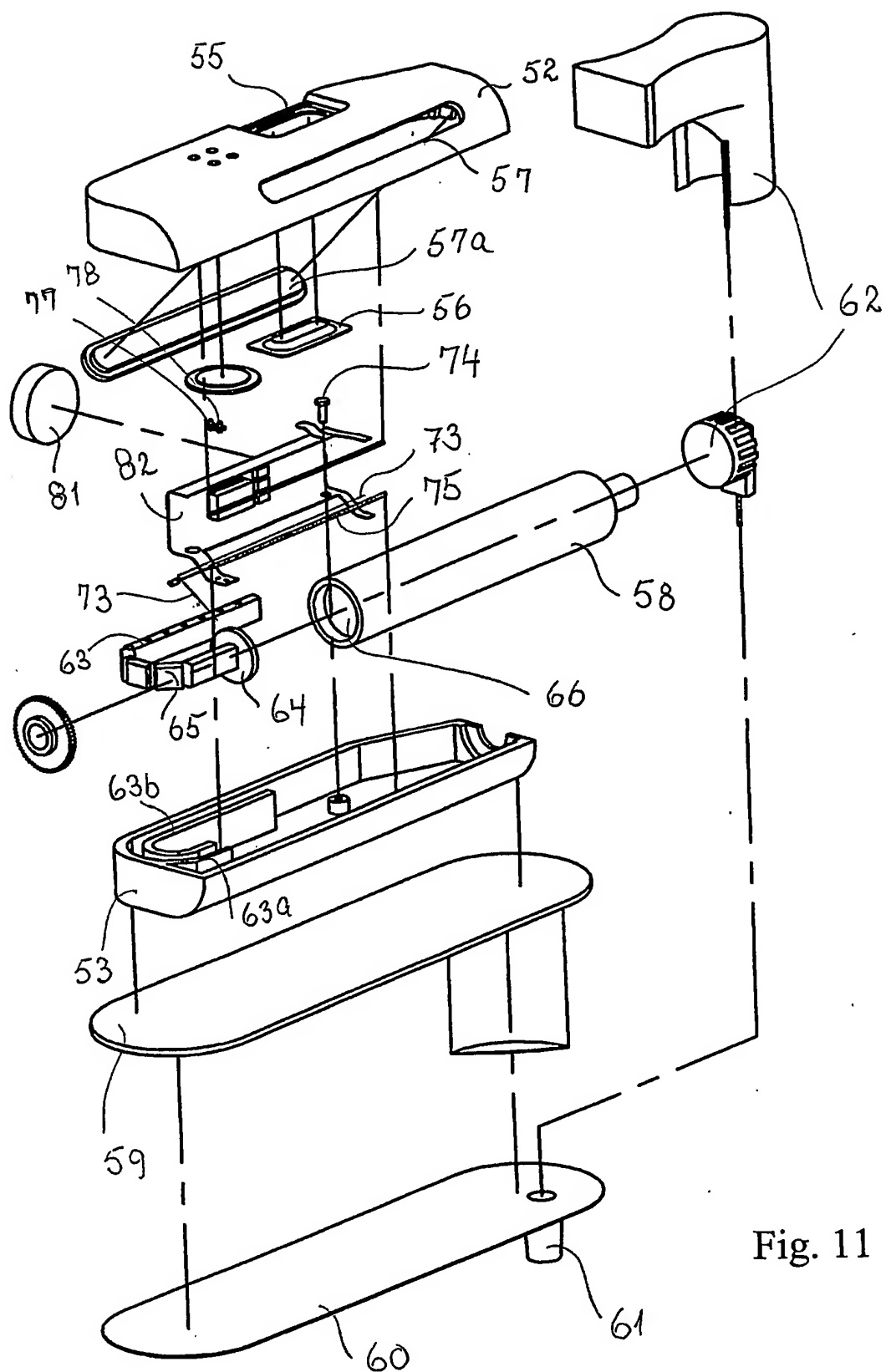


Fig. 11

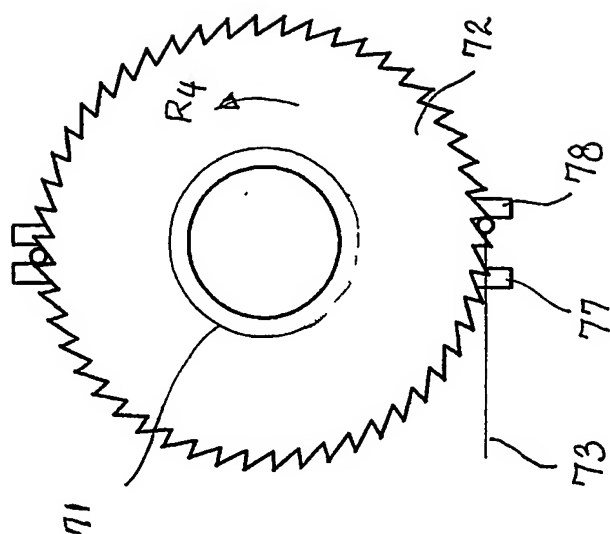


Fig. 12a

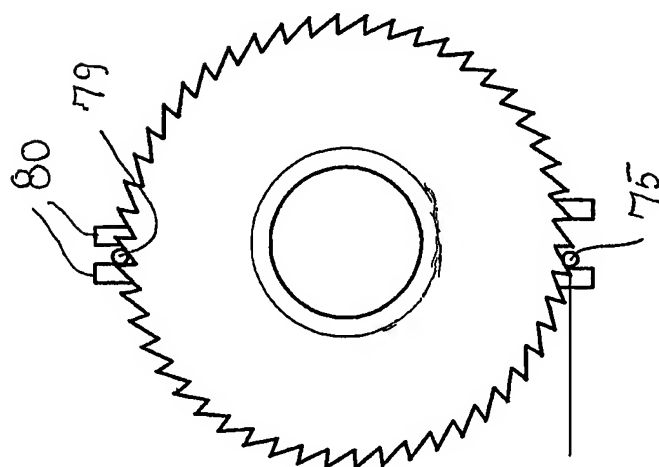


Fig. 12b

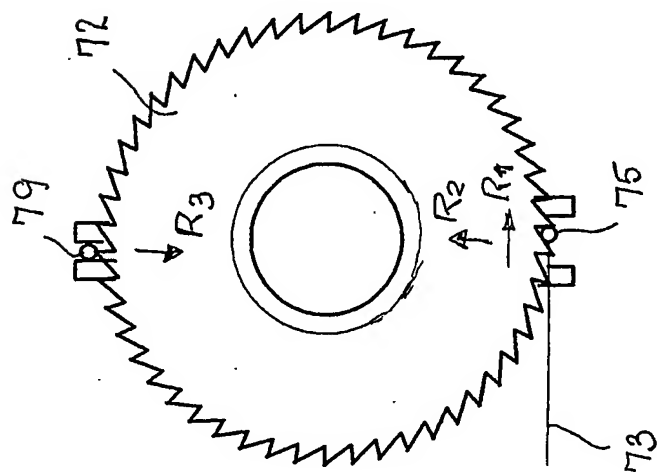


Fig. 12c

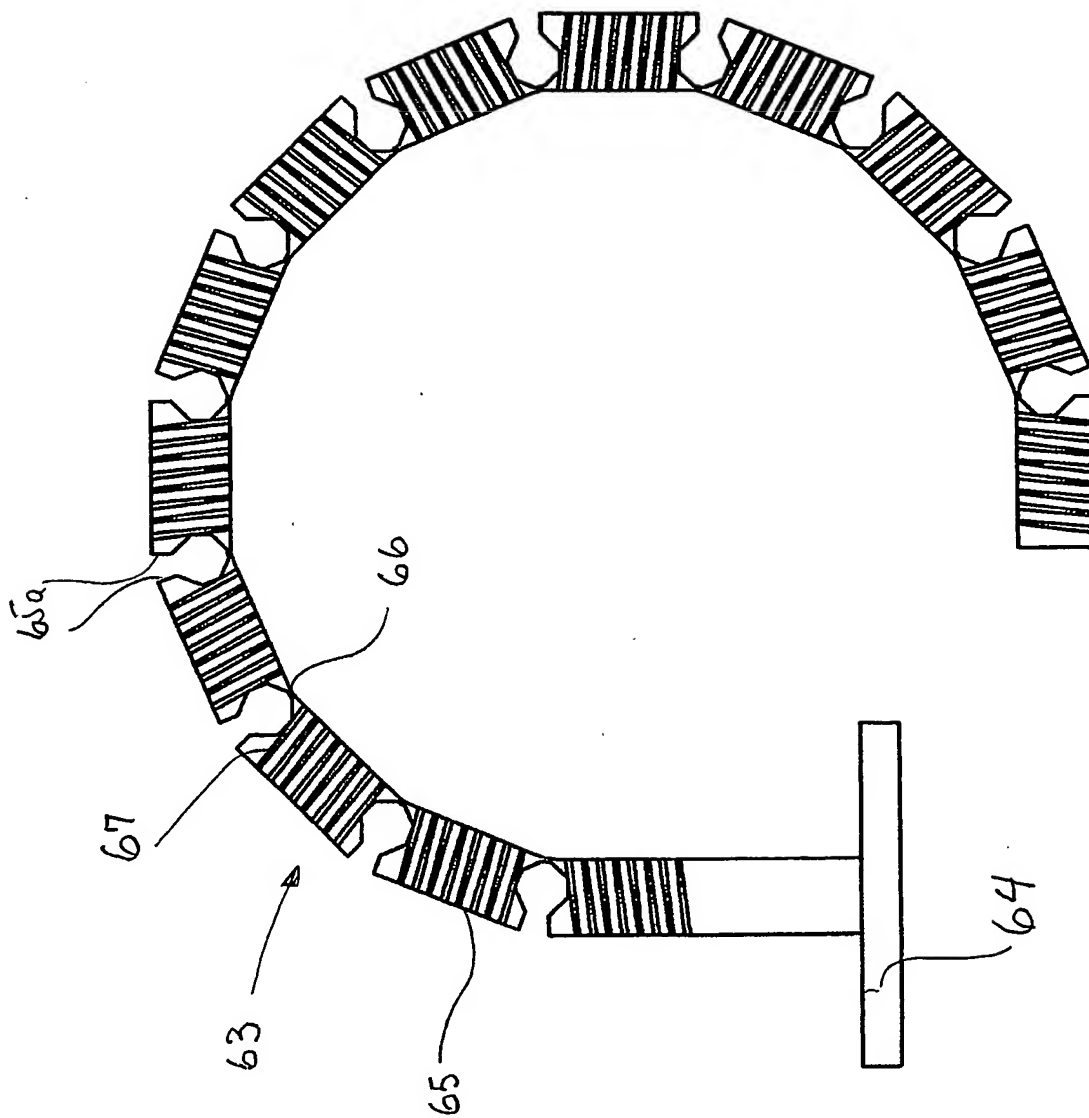


Fig. 13

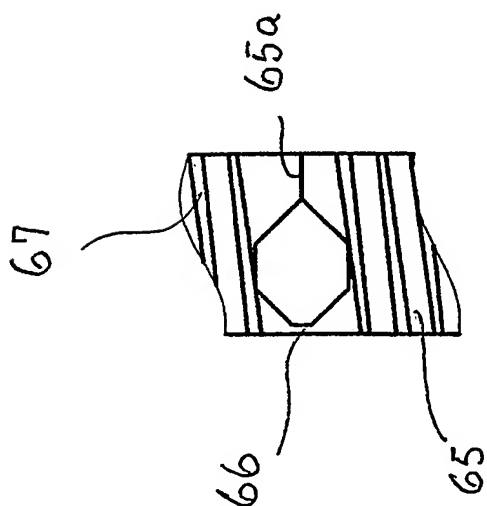


Fig. 14a

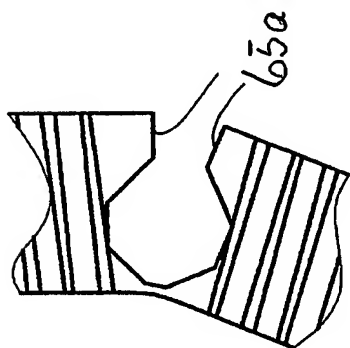


Fig. 14b

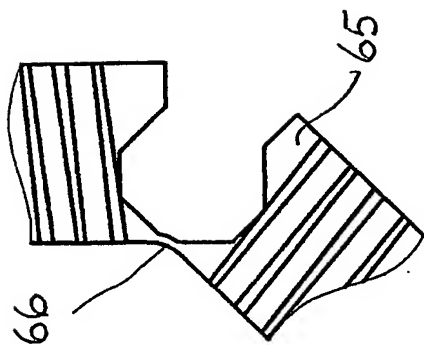


Fig. 14c

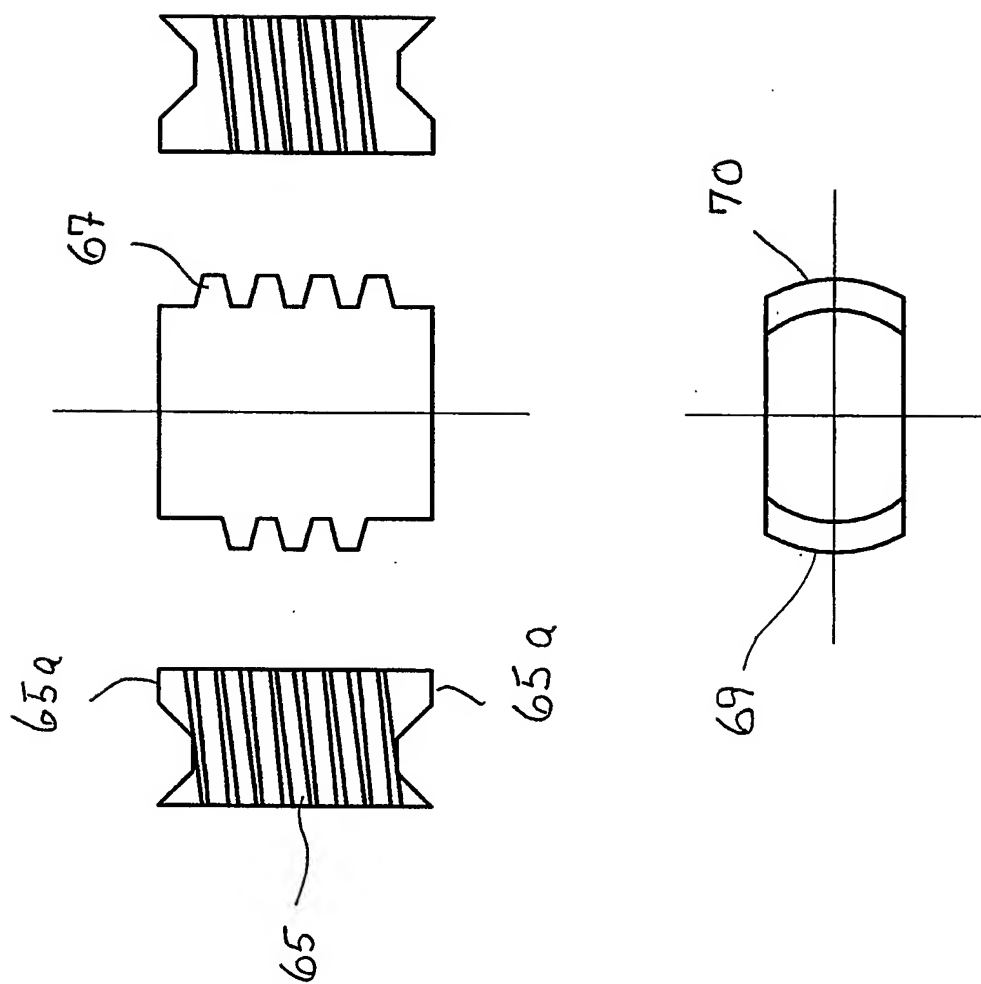


Fig. 15

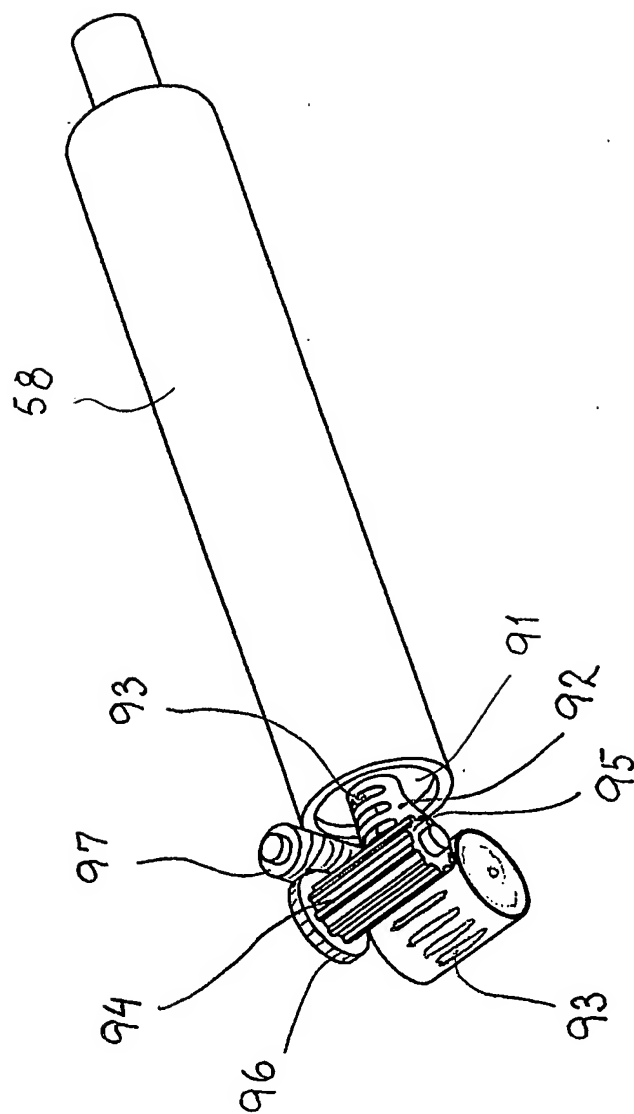


Fig. 16

Fig. 17

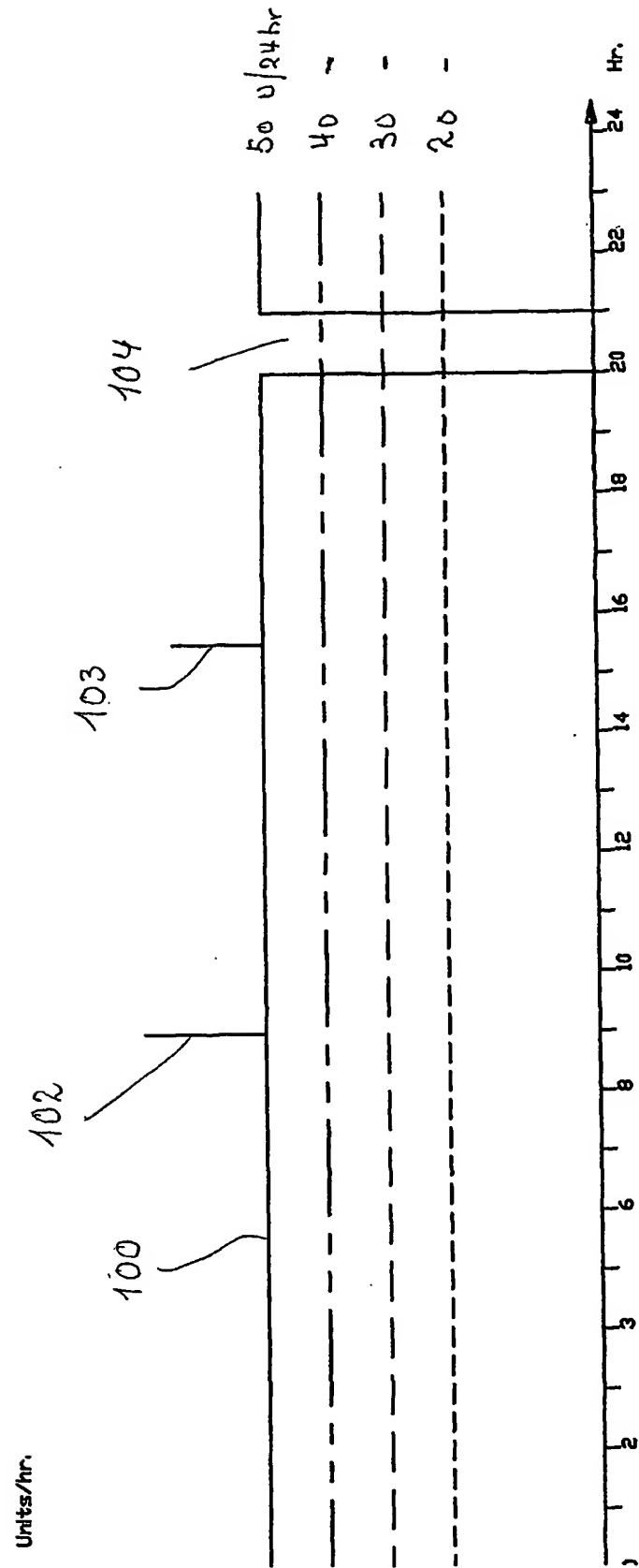


Fig. 18

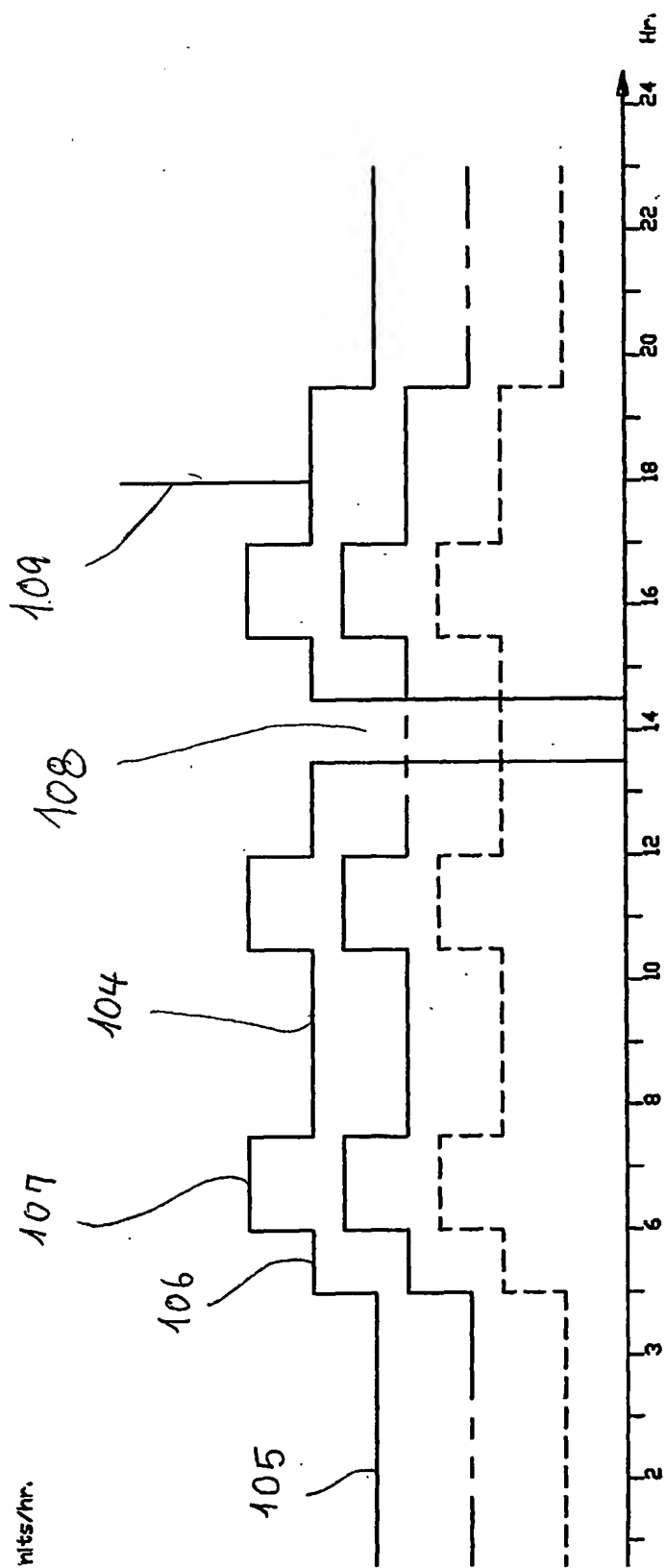
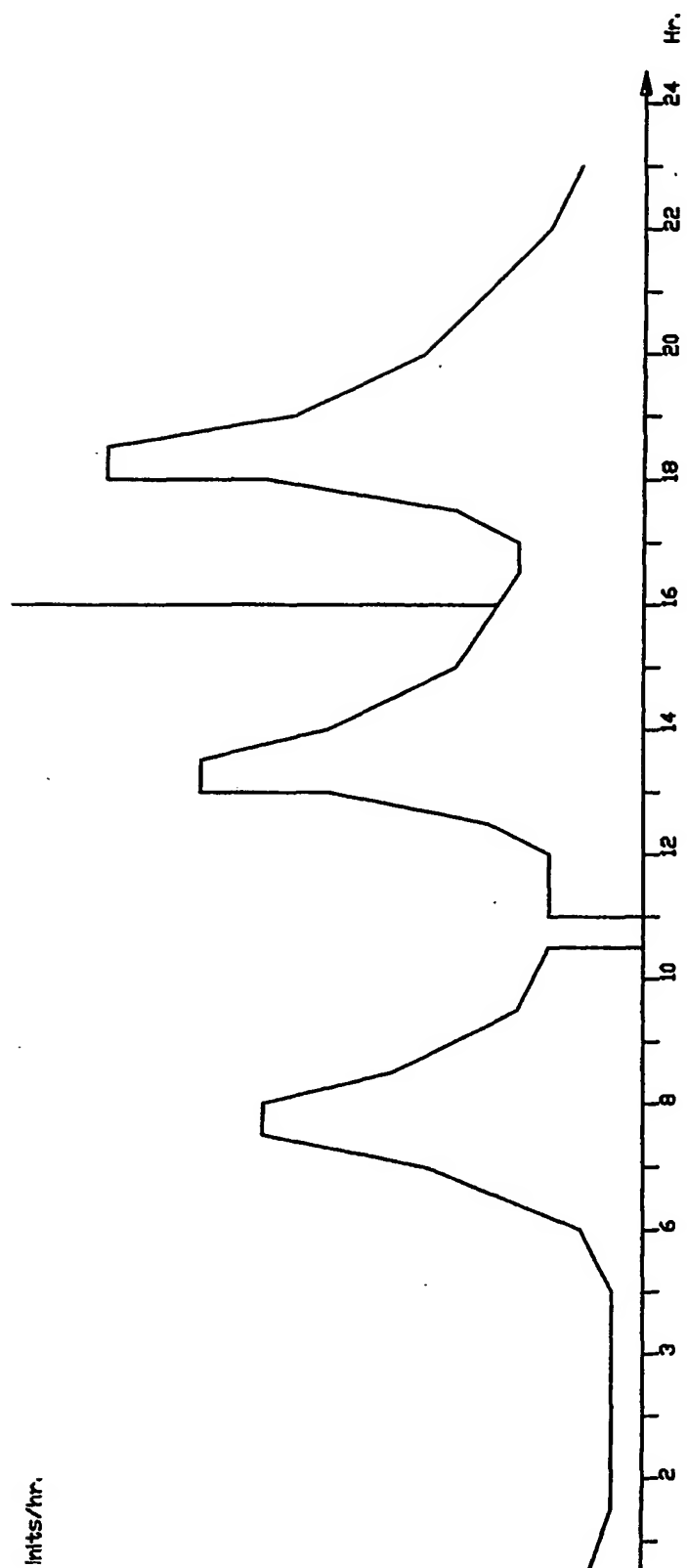


Fig. 19



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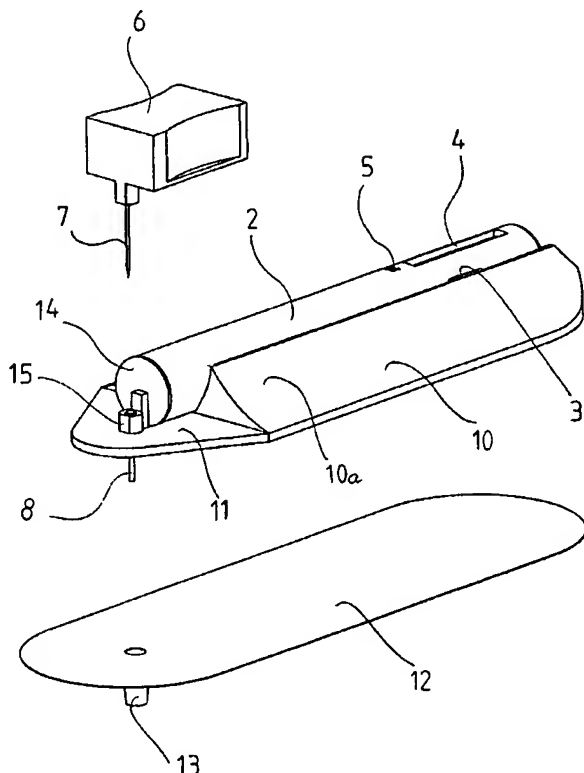
(74) Agent: **BUDDE, SCHOU & OSTENFELD A/S**; Vester Søgade 10, DK-1601 Copenhagen V (DK).

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[Continued on next page]

(54) Title: A DISPOSABLE, WEARABLE INSULIN DISPENSING DEVICE, A COMBINATION OF SUCH A DEVICE AND A PROGRAMMING CONTROLLER AND A METHOD OF CONTROLLING THE OPERATION OF SUCH A DEVICE



(57) Abstract: A disposable, wearable, self-contained insulin dispensing device comprising a housing 2, an insulin source in said housing and adapted for pumping insulin from said insulin source to a catheter 8 for injection of insulin in a user of the device, the catheter being associated with the housing and projecting generally perpendicularly to a generally planar surface of the housing intended for abutting a skin surface of the user, an adhesive layer 11 being provided on the planar surface for adhering the surface to the skin surface, and a removable release sheet 12 covering the adhesive layer for protecting the adhesive layer prior to use of the device, the release sheet being provided with catheter protection means 13 to enclose and protect an end portion of the catheter such that removal of the release sheet for exposing the adhesive layer exposes the end portion, and the pump means comprising an actuator comprising a shape memory alloy wire.

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ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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INTERNATIONAL SEARCH REPORT

Inte Application No
PCT/DK 03/00916

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According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 48546 A (ELAN CORP PLC ;YAGIL GIL (IL); CARMEL EHOUD (IL); GROSS JOSEPH (IL) 30 September 1999 (1999-09-30) page 23, line 4 -page 24, line 5 page 14, line 12 -page 15, line 9	1,2,6-9, 11,12,28
A	---	26
X	WO 02 40083 A (INSULET CORP) 23 May 2002 (2002-05-23) page 5, line 1 - line 23 page 11, line 1 -page 12, line 27	6-9,26, 28
A	---	1,27
P,X	WO 03 103763 A (INSULET CORP) 18 December 2003 (2003-12-18) page 11, line 26 -page 13, line 29 page 17, line 19 -page 18, line 15	4,6-9, 26,28,31
P,A	---	1,11
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Date of the actual completion of the international search 4 August 2004		Date of mailing of the international search report 27 AUG. 2004
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer BO GUSTAVSSON / ELY

INTERNATIONAL SEARCH REPORT

Int'l Application No
PCT/DK 03/00916

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 21457 A (ELAN MED TECH ;GROSS JOSEPH (IE); LAVI GILAD (IL); TSALS IZRAIL (U) 19 June 1997 (1997-06-19) page 17, line 3 - line 14; figure 4	1,2
A	---	11,12
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A	---	7-9,28
A	WO 01 91833 A (NOVO NORDISK AS) 6 December 2001 (2001-12-06) page 17, line 1 - line 23 abstract	3,6,13, 19,26, 27,29,30
A	---	
A	WO 02 100469 A (DAVIES MICHAEL BIRSHA ;JONES ANTHONY PATRICK (GB); GLAXO GROUP LTD) 19 December 2002 (2002-12-19) page 11, line 16 -page 15, line 7 page 31, line 8 -page 33, line 13 -----	3,4,6, 13-17, 26,27, 29,30

INTERNATIONAL SEARCH REPORT

lational application No.
PCT/DK 03/00916

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1,2,13,19-27

I: Claims 1, 2, 13 and 19-27 directed to a disposable, wearable, self-contained medicine dispensing device comprising a removable, protective release sheet covering a planar surface of the dispensing device housing.

2. Claims: 3,11,12,19-27,29 , 30

II: Claims 3, 11, 12, 19-27, 29 and 30 directed to a disposable, wearable, self-contained medicine dispensing device comprising recording/playback means arranged inside the housing, such that verbal messages may be recorded and played back and a method for controlling the operation of the dispensing device.

3. Claims: 4,5,11,12,14-27

III: Claims 4, 5, 11, 12 and 14-27 directed to a disposable, wearable, self-contained medicine dispensing device comprising a pump means, the actuator of which comprising shape memory alloy wire and a method for controlling the operation of the dispensing device.

4. Claims: 6-12,19-28 , 31

IV: Claims 6-12, 19-28 and 31 directed to a disposable, wearable, self-contained medicine dispensing device comprising controlling means for controlling the operation of a pump actuator.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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